



### General

#### Guideline Title

MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy.

### Bibliographic Source(s)

Lalla RV, Bowen J, Barasch A, Elting L, Epstein J, Keefe DM, McGuire DB, Migliorati C, Nicolatou-Galitis O, Peterson DE, Raber-Durlacher JE, Sonis ST, Elad S, Mucositis Guidelines Leadership Group of the MASCC/ISOO [trunc]. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2014 May 15;120(10):1453-61. [40 references] PubMed

### Guideline Status

This is the current release of the guideline.

This guideline updates a previous version: Keefe DM, Schubert MM, Elting LS, Sonis ST, Epstein JB, Raber-Durlacher JE, Migliorati CA, McGuire DB, Hutchins RD, Peterson DE, Mucositis Study Section of the Multinational Association of Supportive Care in Cancer, International Society for Oral Oncology. Updated clinical practice guidelines for the prevention and treatment of mucositis. Cancer. 2007 Mar 1;109(5):820-31. [58 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

# Regulatory Alert

## FDA Warning/Regulatory Alert

Note from the National Guideline Clearinghouse: This guideline references a drug(s) for which important revised regulatory and/or warning information has been released.

• March 22, 2016 – Opioid pain medicines : The U.S. Food and Drug Administration (FDA) is warning about several safety issues with the entire class of opioid pain medicines. These safety risks are potentially harmful interactions with numerous other medications, problems with the adrenal glands, and decreased sex hormone levels. They are requiring changes to the labels of all opioid drugs to warn about these risks.

## Recommendations

# Major Recommendations

The grades of recommendations (Recommendation, Suggestion, and No Guideline Possible) and levels of evidence (I-V) are defined at the end of the "Major Recommendations" field.

Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) Clinical Practice Guidelines for Gastrointestinal Mucositis (Not Including the Oral Cavity) â€∢

Recommendations in Favor of an Intervention (i.e., strong evidence supports effectiveness in the treatment setting listed)

- 1. The panel *recommends* that intravenous amifostine be used, at a dose of ≥340 mg/m², to *prevent* radiation proctitis in patients receiving radiation therapy (II).
- 2. The panel *recommends* that octreotide, at a dose of ≥100 µg subcutaneously twice daily, be used to *treat* diarrhea induced by standard- or high-dose chemotherapy associated with hematopoietic stem cell transplantation (HSCT), if loperamide is ineffective (II).

Suggestions in Favor of an Intervention (i.e., weaker evidence supports effectiveness in the treatment setting listed)

- 1. The panel *suggests* that intravenous amifostine be used to *prevent* esophagitis induced by concomitant chemotherapy and radiation therapy in patients with non-small cell lung carcinoma (III).
- 2. The panel suggests that sucralfate enemas be used to treat chronic radiation-induced proctitis in patients with rectal bleeding (III).
- 3. The panel *suggests* that systemic sulfasalazine, at a dose of 500 mg administered orally twice a day, be used to *prevent* radiation-induced enteropathy in patients receiving radiation therapy to the pelvis (II).
- 4. The panel *suggests* that probiotics containing *Lactobacillus* species be used to *prevent* diarrhea in patients receiving chemotherapy and/or radiation therapy for a pelvic malignancy (III).
- 5. The panel *suggests* that hyperbaric oxygen be used to *treat* radiation-induced proctitis in patients receiving radiation therapy for a solid tumor (IV).

Recommendations Against an Intervention (i.e., strong evidence indicates lack of effectiveness in the treatment setting listed)

- 1. The panel *recommends* that systemic sucralfate, administered orally, *not* be used to *treat* gastrointestinal mucositis in patients receiving radiation therapy for a solid tumor (I).
- 2. The panel *recommends* that 5-acetyl salicylic acid (ASA), and the related compounds mesalazine and olsalazine, administered orally, *not* be used to *prevent* acute radiation-induced diarrhea in patients receiving radiation therapy for a pelvic malignancy (I).
- 3. The panel *recommends* that misoprostol suppositories *not* be used to *prevent* acute radiation-induced proctitis in patients receiving radiation therapy for prostate cancer (I).

Suggestions Against an Intervention (i.e., weaker evidence indicates lack of effectiveness in the treatment setting listed)

None

#### MASCC/ISOO Clinical Practice Guidelines for Oral Mucositis

Recommendations in Favor of an Intervention (i.e., strong evidence supports effectiveness in the treatment setting listed)

- 1. The panel *recommends* that 30 min of oral cryotherapy be used to *prevent* oral mucositis in patients receiving bolus 5-fluorouracil chemotherapy (II).
- 2. The panel *recommends* that recombinant human keratinocyte growth factor-1 (KGF-1/palifermin) be used to *prevent* oral mucositis (at a dose of 60 µg/kg per day for 3 days prior to conditioning treatment and for 3 days after transplant) in patients receiving high-dose chemotherapy and total body irradiation, followed by autologous stem cell transplantation, for a hematological malignancy (II).
- 3. The panel *recommends* that low-level laser therapy (wavelength at 650 nm, power of 40 mW, and each square centimeter treated with the required time to a tissue energy dose of 2 J/cm<sup>2</sup>), be used to *prevent* oral mucositis in patients receiving HSCT conditioned with high-dose chemotherapy, with or without total body irradiation (II).
- 4. The panel *recommends* that patient-controlled analgesia with morphine be used to *treat* pain due to oral mucositis in patients undergoing HSCT (II).
- 5. The panel *recommends* that benzydamine mouthwash be used to *prevent* oral mucositis in patients with head and neck cancer receiving moderate dose radiation therapy (up to 50 Gy), without concomitant chemotherapy (I).

Suggestions in Favor of an Intervention (i.e., weaker evidence supports effectiveness in the treatment setting listed)

1. The panel *suggests* that oral care protocols be used to *prevent* oral mucositis in all age groups and across all cancer treatment modalities (III).

- 2. The panel *suggests* that oral cryotherapy be used to *prevent* oral mucositis in patients receiving high-dose melphalan, with or without total body irradiation, as conditioning for HSCT (III).
- 3. The panel *suggests* that low-level laser therapy (wavelength around 632.8 nm) be used to *prevent* oral mucositis in patients undergoing radiotherapy, without concomitant chemotherapy, for head and neck cancer (III).
- 4. The panel *suggests* that transdermal fentanyl may be effective to *treat* pain due to oral mucositis in patients receiving conventional or high-dose chemotherapy, with or without total body irradiation (III).
- 5. The panel *suggests* that 0.2% morphine mouthwash may be effective to *treat* pain due to oral mucositis in patients receiving chemoradiation for head and neck cancer (III).
- 6. The panel suggests that 0.5% doxepin mouthwash may be effective to treat pain due to oral mucositis (IV).
- 7. The panel *suggests* that systemic zinc supplements administered orally may be of benefit to *prevent* oral mucositis in oral cancer patients receiving radiation therapy or chemoradiation (III).

Recommendations Against an Intervention (i.e., strong evidence indicates lack of effectiveness in the treatment setting listed)

- 1. The panel *recommends* that PTA (polymyxin, tobramycin, amphotericin B) and BCoG (bacitracin, clotrimazole, gentamicin) antimicrobial lozenges and PTA paste *not* be used to *prevent* oral mucositis in patients receiving radiation therapy for head and neck cancer (II).
- 2. The panel *recommends* that iseganan antimicrobial mouthwash *not* be used to *prevent* oral mucositis in patients receiving high-dose chemotherapy, with or without total body irradiation, for HSCT (II), or in patients receiving radiation therapy or concomitant chemoradiation for head and neck cancer (II).
- 3. The panel *recommends* that sucralfate mouthwash *not* be used to *prevent* oral mucositis in patients receiving chemotherapy for cancer (I), or in patients receiving radiation therapy (I) or concomitant chemoradiation (II) for head and neck cancer.
- 4. The panel *recommends* that sucralfate mouthwash *not* be used to *treat* oral mucositis in patients receiving chemotherapy for cancer (I), or in patients receiving radiation therapy (II) for head and neck cancer.
- 5. The panel *recommends* that intravenous glutamine *not* be used to *prevent* oral mucositis in patients receiving high-dose chemotherapy, with or without total body irradiation, for HSCT (II).

Suggestions Against an Intervention (i.e., weaker evidence indicates lack of effectiveness in the treatment setting listed)

- 1. The panel *suggests* that chlorhexidine mouthwash *not* be used to *prevent* oral mucositis in patients receiving radiation therapy for head and neck cancer (III).
- 2. The panel *suggests* that granulocyte-macrophage-colony-stimulating factor mouthwash *not* be used to *prevent* oral mucositis in patients receiving high-dose chemotherapy, for autologous or allogeneic stem cell transplantation (II).
- 3. The panel *suggests* that misoprostol mouthwash *not* be used to *prevent* oral mucositis in patients receiving radiation therapy for head and neck cancer (III).
- 4. The panel *suggests* that systemic pentoxifylline, administered orally, *not* be used to *prevent* oral mucositis in patients undergoing bone marrow transplantation (III).
- 5. The panel *suggests* that systemic pilocarpine, administered orally, *not* be used to *prevent* oral mucositis in patients receiving radiation therapy for head and neck cancer (III), or in patients receiving high-dose chemotherapy, with or without total body irradiation, for HSCT (II).

#### **Definitions**:

Criteria for Each Level of Evidence\*

I	Evidence obtained from meta-analysis of multiple, well-designed, controlled studies; randomized trials with low false-positive and false-negative errors (high power).
II	Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or false-negative errors (low power).
III	Evidence obtained from well-designed, quasi-experimental studies, such as nonrandomized, controlled single-group, pretest-posttest comparison, cohort, time or matched case-control series.
IV	Evidence obtained from well-designed, non-experimental studies, such as comparative and correlational descriptive and case studies.
V	Evidence obtained from case reports and clinical examples.

#### Criteria for Each Guideline Category\*

Recommendation	Reserved for guidelines that are based on level I or level II evidence.
Suggestion	Used for guidelines that are based on level III, level IV and level V evidence; this implies panel consensus on the interpretation of this evidence.
No guideline possible	Used when there is insufficient evidence on which to base a guideline; this implies (1) that there is little or no evidence regarding the practice in question or (2) that the panel lacks consensus on the interpretation of existing evidence.

<sup>\*</sup>Adapted from Somerfield M, Padberg J, Pfister D, et al. ASCO clinical practice guidelines: process, progress, pitfalls, and prospects. Classic Pap Curr Comments. 2000;4:881-886.

### Clinical Algorithm(s)

None provided

# Scope

### Disease/Condition(s)

Oral and gastrointestinal mucositis secondary to cancer therapy

# **Guideline Category**

Management

Prevention

Treatment

# Clinical Specialty

Dentistry

Hematology

Nursing

Oncology

Otolaryngology

Preventive Medicine

Radiation Oncology

### **Intended Users**

Advanced Practice Nurses

Allied Health Personnel

**Dentists** 

Nurses

Physician Assistants

Physicians

### Guideline Objective(s)

To provide updated evidence-based clinical practice guidelines for the management (prevention and treatment) of oral and gastrointestinal mucositis secondary to cancer therapy

### **Target Population**

Cancer patients with or at risk of oral or gastrointestinal mucositis

#### Interventions and Practices Considered

#### Prevention

- 1. Gastrointestinal mucositis
  - Intravenous amifostine
  - Systemic sulfasalazine
  - Probiotics including Lactobacillus species
- 2. Oral mucositis
  - Cryotherapy
  - Keratinocyte growth factor-1 (palifermin)
  - Low-level laser therapy
  - Benzydamine mouthwash
  - Oral care protocols
  - Systemic zinc supplements

#### Management/Treatment

- 1. Gastrointestinal mucositis
  - Octreotide and loperamide
  - Sucralfate enemas
  - Hyperbaric oxygen
- 2. Oral mucositis
  - Patient controlled analgesia with morphine
  - Transdermal fentanyl
  - 0.2% morphine mouthwash
  - 0.5% doxepin mouthwash

Note: The following were considered but not recommended: Systemic sucralfate, 5-acetyl salicylic acid (ASA), mesalazine and olsalazine, misoprostol suppositories, PTA (polymyxin, tobramycin, amphotericin B) and BCoG (bacitracin, clotrimazole, gentamicin) antimicrobial lozenges and PTA paste, iseganan antimicrobial mouthwash, sucralfate mouthwash, intravenous glutamine, chlorhexidine mouthwash, granulocytemacrophage-colony-stimulating factor mouthwash, misoprostol mouthwash, systemic pentoxifylline, systemic pilocarpine.

## Major Outcomes Considered

- Effectiveness of preventive interventions
- Effectiveness of treatment interventions

# Methodology

#### Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

### Description of Methods Used to Collect/Select the Evidence

#### Literature Searches

Literature search strategies were developed by initially creating lists of known interventions for oral and gastrointestinal mucositis. The organizers produced the lists and received feedback from the section heads regarding intervention coverage. The research librarian then created search statements which linked the intervention keywords together with keywords related to cancer, its treatment and mucosal injury. Searches were then conducted through the OVID interface to MEDLINE and limited to human research published in English. For mucositis clinical interventions, all papers indexed in MEDLINE before 31 December 2010 were included in the review. This approach identified over 8,000 articles. In addition to database searches, the reference lists of previous guidelines papers and Cochrane meta-analyses were searched for any additional studies. Access to specific section searches is available on request from the authors.

Due to the large number and diverse range of interventions, the reviewers and articles were organized into 8 clinical sections. One section focused on gastrointestinal mucositis and 7 sections examined the following classes of interventions for oral mucositis: 1) basic oral care; 2) growth factors and cytokines; 3) anti-inflammatory agents; 4) antimicrobials, coating agents, anesthetics, and analgesics; 5) laser and other light therapy; 6) cryotherapy; and 7) natural and miscellaneous agents. Each of the 8 sections had a section head,  $\geq 1$  co-section heads, and 5 to 10 reviewers. All participants were calibrated to ensure consistency in the application of the review criteria. In addition, reviewers and section heads were provided with role-specific written instructions and a manual detailing the procedures. Each article was independently reviewed by 2 reviewers.

The output of the search strategies were exported into Endnote libraries. An Endnote library containing the articles identified was sent to each section head to select papers for retrieval. Section heads removed articles which did not meet specified inclusion criteria and returned the updated libraries to the organizers. Standard flow charts were provided to control numbers of included and excluded studies as suggested in the "PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate health care interventions: explanation and elaboration." The workflow for the review is shown in Figure 1 in the original guideline document. Inclusion and exclusion criteria were as follows.

#### Inclusion Criteria

- 1. Published clinical research papers testing an intervention (prevention or treatment) for mucositis or meta-analyses of such studies
- 2. English language
- 3. Published in a peer-reviewed journal (note: online publication on the journal's website is adequate for inclusion)
- 4. Indexed in Medline on or before 31 December 2010
- 5. All age groups

#### **Exclusion Criteria**

- 1. Papers that do not report the effects of an intervention on mucositis or on related outcomes such as mucositis-associated pain
- 2. Animal studies or in vitro studies
- 3. Literature reviews
- 4. Papers published in a language other than English

Selected papers were retrieved and made accessible to reviewers through a password-protected online database.

In between the formal updates conducted every few years, MASCC/ISOO informally monitors the literature for pivotal studies that could result in a modification of the guidelines.

#### Number of Source Documents

The literature search identified 8279 articles, 1032 of which were retrieved for detailed evaluation based on titles and abstracts; of these, 570 articles qualified for final inclusion in the systematic reviews.

### Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

### Rating Scheme for the Strength of the Evidence

Criteria for Each Level of Evidence

I	Evidence obtained from meta-analysis of multiple, well-designed, controlled studies; randomized trials with low false-positive and false-negative errors (high power).
II	Evidence obtained from at least one well-designed experimental study; randomized trials with high false-positive and/or false-negative errors (low power).
III	Evidence obtained from well-designed, quasi-experimental studies, such as nonrandomized, controlled single-group, pretest-posttest comparison, cohort, time or matched case-control series.
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Adapted from Somerfield M, Padberg J, Pfister D, et al. ASCO clinical practice guidelines: process, progress, pitfalls, and prospects. Classic Pap Curr Comments. 2000;4:881-886.

### Methods Used to Analyze the Evidence

Systematic Review

## Description of the Methods Used to Analyze the Evidence

Forms and Calibration

To ensure consistency in data extraction, quality assessment and data synthesis, a series of manuals and instructions files were developed and delivered to all involved. These included an overall instructions manual, and separate instructions for reviewers, and instructions for section heads. Forms developed for this process included an Excel review form for individual reviewers, and a separate Excel form for the section heads to complete.

Each reviewer and section head/co-head also underwent calibration. The calibration consisted of blinded review of the paper by Silva et al. (2010), a randomized controlled trial (RCT) investigating low-level laser therapy for prevention of oral mucositis, before receiving the calibration key with standardised responses. According to this key, the reviewers were able to adjust future reviews. In addition, calibration teleconferences were conducted to discuss and ensure correct usage of the electronic review forms.

#### Data Extraction and Synthesis

Each paper was independently reviewed by two reviewers. Each reviewer extracted up to 66 fields of data per paper and entered them in the reviewer form. The section head received two separate review forms for each paper. The section head then combined the two reviews into one final review in the section heads Excel form. Discrepancies in any field between the two reviewers were resolved by the section head, by reference to the publication and/or discussion with reviewers, as appropriate. In another sheet of the section head form, data from all the different papers for each intervention were put together so that the overall data for each intervention could be evaluated. In yet another sheet of the section head form, the most critical fields needed for guideline development were entered. Interventions were separated based on (1) the aim of the intervention: prevention or treatment of mucositis; (2) the treatment setting, radiotherapy, chemotherapy, chemoradiotherapy or high-dose conditioning therapy

for hematopoietic stem cell transplant and (3) the route of administration of the intervention.

#### Criteria Used to Evaluate Literature

The quality of the reviewed literature was assessed by identifying flaws in study design and methods as part of the data extraction process. Identification of flaws in study design and reporting followed the guidelines published by Hadorn et al. This allowed reviewers to assign major and minor flaws to each study (see Table 1 in the methodology companion [see the "Availability of Companion Documents" field]). As part of the data extraction process, each reviewer identified major and minor flaws in the reviewed papers. In case of discrepancy between the two reviewers, the respective section head/co-head made the final decision on the list of major and minor flaws for each study. Less than 5 % of all studies reviewed were found to have no major flaws.

#### Assignment of a Level of Evidence

Once the major and minor flaws in each paper were identified, the overall body of evidence for a given intervention was assessed. Based on this, the section head assigned a level of evidence for each paper and for each intervention for each specific indication (prevention or treatment of mucositis) and route of administration, in each population. The assigning of a level of evidence was based on criteria published by Somerfield et al. (see the "Rating Scheme for the Strength of the Evidence" field). These criteria allocate levels of evidence based on the type of study and according to whether or not a study is "well-designed". In order to minimize subjectivity in determining whether a study is well-designed or not, we defined a "well-designed study" as a study with no major flaws, per the Hadorn criteria. If a study did not meet this definition of well designed, it was assigned a level of evidence one level below what it would have received if it had no major flaws. For example, a single RCT with no major flaws was assigned level II; however, if it had one or more major flaws, it was assigned level III. The overall body of evidence for an intervention was assigned with the level of evidence of the highest-ranking individual paper available for that intervention. For example, if there were three papers for a given intervention, one RCT with major flaws (level III) and two case—control studies with major flaws (level IV), an overall level of evidence of III was assigned for that intervention. An exception to this rule was the rare situation in which there were two or more well-designed RCTs (level II) for an intervention. In this case, an overall level of evidence of I was assigned for the intervention.

#### Methods Used to Formulate the Recommendations

Expert Consensus (Consensus Development Conference)

## Description of Methods Used to Formulate the Recommendations

#### Committee Organization

The Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) Mucositis Study Group (MSG) was formed in 1998. In 2010, all academic members of the MSG were invited to participate in the present update. Two independent observers and a research librarian were also invited to participate in the update process. Additional personnel were recruited to retrieve and organize the large number of research papers needing review. All together, almost 100 people were involved in the effort. To provide structure to the large committee, it was organized hierarchically to include an organizer, co-organizers, section heads, co-section heads and reviewers. Each section consisted of a section head, one or two co-section heads and five to ten reviewers.

The role of the organizer was to oversee the whole process and ultimately translate the aims into action by the sections. The co-organizers were responsible for managing the sections (allocated half each) and providing day to day communication between the tiers. The section heads were allocated to one section each, according to previous guidelines experience and research interest, and were invited to name section co-heads. The role of the section head was to allocate papers to each reviewer in their group, collect and cross check reviews, provide summaries of the results and generate provisional guidelines, while the co-section head provided assistance in this role. The role of the reviewers was to conduct quality reviews of all papers allocated to them, and complete the standardised review form, before returning these to their section head. The two independent observers were present at the Guidelines Update Meeting to provide input and ensure transparency and consistency during development of guidelines. The research librarian constructed the literature searches and conducted the database searches with input from the organizer and co-organizers.

### Development of Guidelines

The evidence level for each intervention facilitated guideline development. Based on the methodology described in Somerfield et al. (see the "Rating Scheme for the Strength of the Recommendations" field), guidelines were assigned to one of three possible categories: Recommendation, Suggestion or No Guideline Possible. Specifically, level I or II evidence was required to form a recommendation, which could only be achieved by

one or more randomized controlled trials (RCTs) without any major flaws. A suggestion could be formed using level III or lower evidence. However, in practice, a suggestion was only created when more than one study existed for the intervention in the specific setting. If only one study existed, or if there was no panel consensus on the interpretation of the literature, no suggestion was possible. Furthermore, any intervention that showed evidence in the literature of worsening mucositis or inducing severe side effects was noted specifically by the section head and the risk—benefit ratio was discussed by the wider group. In practice, this could be one of the reasons for the development of a guideline against the use of an agent. Directions for clinical practice were specified based on the aim, setting and administration for each intervention. The provisional guidelines were discussed at a Guidelines Update Meeting attended by over 60 members of the committee and two independent observers. Committee consensus was achieved before finalizing guidelines.

### Rating Scheme for the Strength of the Recommendations

Criteria for Each Guideline Category

Recommendation	Reserved for guidelines that are based on level I or level II evidence.
Suggestion	Used for guidelines that are based on level III, level IV and level V evidence; this implies panel consensus on the interpretation of this evidence.
No guideline possible	Used when there is insufficient evidence on which to base a guideline; this implies (1) that there is little or no evidence regarding the practice in question or (2) that the panel lacks consensus on the interpretation of existing evidence.

Adapted from Somerfield M, Padberg J, Pfister D, et al. ASCO clinical practice guidelines: process, progress, pitfalls, and prospects. Classic Pap Curr Comments. 2000;4:881-886.

### Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

#### Method of Guideline Validation

Peer Review

### Description of Method of Guideline Validation

The provisional guidelines were discussed and finalized at a Guidelines Update Meeting attended by over 60 members of the committee and 2 independent observers. Committee consensus was achieved before finalizing guidelines.

# Evidence Supporting the Recommendations

## Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

# Benefits/Harms of Implementing the Guideline Recommendations

### **Potential Benefits**

Appropriate management and prevention of oral and gastrointestinal mucositis secondary to cancer therapy

#### **Potential Harms**

Any intervention that showed evidence in the literature of worsening mucositis or inducing severe side effects was noted specifically by the section head and the risk—benefit ratio was discussed by the wider group.

# **Qualifying Statements**

### **Qualifying Statements**

- The Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC/ISOO) Mucositis
  Guidelines are developed to facilitate the evidence-based management of mucositis. However, clinicians should also use their own judgment
  in making treatment decisions for individual patients. The guideline authors and the MASCC/ISOO do not guarantee or take responsibility
  for clinical outcomes in individual patients.
- These guidelines refer to the use of the listed agents for the specific indication listed (i.e., the prevention or treatment of mucositis or related symptoms). These guidelines do not apply to the use of the listed agents for other indications. For example, although it is suggested that chlorhexidine mouthwash not be used to prevent oral mucositis in patients receiving head and neck radiation therapy, clinicians may choose to use this agent for other indications in this or other populations.

# Implementation of the Guideline

### Description of Implementation Strategy

The goal of clinical practice guidelines is to improve clinical outcomes by facilitating evidence-based care. To achieve this, it is important for the guidelines to be widely disseminated and, most importantly, adopted into routine practice. Strategies to facilitate guidelines uptake can include open-access publication of the guidelines-related articles and translations into other languages, as well as online resources, including a version suitable for viewing on a smartphone. The Multinational Association of Supportive Care in Cancer/International Society of Oral Oncology (MASCC/ISOO) is also in discussions with relevant organizations to determine how they can work together to minimize duplication of effort and promote the clinical use of supportive care guidelines. The motto of the MASCC/ISOO is "Supportive care makes excellent cancer care possible." In keeping with this, MASCC/ISOO is committed to enhancing the supportive care of oncology patients, with the goal of improving the patient experience and allowing for the delivery of optimal cancer treatment.

See the dissemination and clinical impact companion (see the "Availability of Companion Documents" field) for more information.

## Implementation Tools

Foreign Language Translations

Quick Reference Guides/Physician Guides

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

#### **IOM Domain**

Effectiveness

Patient-centeredness

# Identifying Information and Availability

### Bibliographic Source(s)

Lalla RV, Bowen J, Barasch A, Elting L, Epstein J, Keefe DM, McGuire DB, Migliorati C, Nicolatou-Galitis O, Peterson DE, Raber-Durlacher JE, Sonis ST, Elad S, Mucositis Guidelines Leadership Group of the MASCC/ISOO [trunc]. MASCC/ISOO clinical practice guidelines for the management of mucositis secondary to cancer therapy. Cancer. 2014 May 15;120(10):1453-61. [40 references] PubMed

### Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

2004 (revised 2014 May 15)

### Guideline Developer(s)

International Society for Oral Oncology - Disease Specific Society

Multinational Association of Supportive Care in Cancer - Disease Specific Society

## Source(s) of Funding

The Guidelines Update Meeting was supported by BioAlliance Pharma and Helsinn Healthcare, SA. No honorarium or travel support was provided to the reviewers for participation in the guidelines update effort. No industry representatives attended the guidelines update meeting or participated in the guidelines update effort in any way.

#### Guideline Committee

Mucositis Study Group of the Multinational Association of Supportive Care in Cancer and International Society of Oral Oncology (MASCC-ISOO)

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#### Financial Disclosures/Conflicts of Interest

Dr. Lalla received grants from Evolife Laboratories and BioAlliance Pharma, as well as personal fees from iNova Pharmaceuticals, Sucampo, Cangene, and Ingalpharma outside of the current study. Dr. Elting received a grant from Helsinn Research funding for work outside of the current study. Dr. Epstein received a grant from 3M-Riker Canada for participation in a phase 3 study related to the current work. Dr. Keefe received grants from Helsinn Healthcare, GlaxoSmithKline, and Nestec for work outside of the current study. Dr. Sonis is an employee of Biomodels LLC, has acted as a consultant for Clinical Assistance Programs, acted as a member of the advisory board for Actogenix, acted as an advisor for Avaxia, acted as a biomodels consultant for BioAlliance, acted as a member of the advisory board for Galera, acted as a consultant for Izun, acted as an advisor for PolyMedix, acted as a biomodels consultant for Piramal, received fees as a founder-consultant for Inform Genomics, acted as a member of the advisory board of and as a consultant for Pfizer, acted as a member of the advisory board of Reata, acted as a consultant for Access, and acted as a biomodel consultant for Novartis and Merck for work outside of the current study. Dr. Sonis also holds the following patents that are broadly relevant to the current work: US Patent 6458777, US Patent 6663850, US Patent 6713463, US Patent 6841578B2, and US Patent 7297123.

### **Guideline Status**

This is the current release of the guideline.

This guideline updates a previous version: Keefe DM, Schubert MM, Elting LS, Sonis ST, Epstein JB, Raber-Durlacher JE, Migliorati CA, McGuire DB, Hutchins RD, Peterson DE, Mucositis Study Section of the Multinational Association of Supportive Care in Cancer, International Society for Oral Oncology. Updated clinical practice guidelines for the prevention and treatment of mucositis. Cancer. 2007 Mar 1;109(5):820-31. [58 references]

This guideline meets NGC's 2013 (revised) inclusion criteria.

## Guideline Availability

Electronic comics, Assilable from the Multimational Association of Commenting Comment (MACCC) Web site	
Electronic copies: Available from the Multinational Association of Supportive Care in Cancer (MASCC) Web site	

## Availability of Companion Documents

The following are available:

MASCC/ISOO evidence-based clinical practice guidelines for the management of mucositis secondary to cancer therapy. Summary. 2014
 Nov 7. 6 p. Electronic copies: Available from the Multinational Association of Supportive Care in Cancer (MASCC) Web site

. A variety of translations are also available from the MASCC Web site
• Lalla RV. The MASCC/ISOO mucositis guidelines update: introduction to the first set of articles. Support Care Cancer. 2013;21:301–2.
Electronic copies: Available from the Supportive Care in Cancer Web site
• Bowen JM, Elad S, Hutchins RD, Lalla RV, for the Mucositis Study Group of the Multinational Association of Supportive Care in
Cancer/International Society of Oral Oncology (MASCC/ISOO). Methodology for the MASCC/ISOO mucositis clinical practice
guidelines update. Support Care Cancer. 2013;21:303–8. Electronic copies: Available from the Supportive Care in Cancer Web site
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Cancer/International Society of Oral Oncology (MASCC/ISOO). Development of the MASCC/ISOO clinical practice guidelines for
mucositis: considerations underlying the process. Support Care Cancer. 2013;21:309–12. Electronic copies: Available from the Supportive
Care in Cancer Web site
• Lalla RV, Ashbury FD. The MASCC/ISOO mucositis guidelines: dissemination and clinical impact. Support Care Cancer. 2013;21:3161–
3. Electronic copies: Available from the Supportive Care in Cancer Web site
In addition the systematic reviews conducted for the guideline are available from the MASCC Web site

#### Patient Resources

None available

#### **NGC Status**

This NGC summary was completed by ECRI Institute on April 17, 2008. The information was verified by the guideline developer on May 19, 2008. This summary was updated by ECRI Institute on July 26, 2010 following the U.S. Food and Drug Administration (FDA) advisory on Proton Pump Inhibitors (PPI). This summary was updated by ECRI Institute on November 19, 2014. The updated information was verified by the guideline developer on November 25, 2014. This summary was updated by ECRI Institute on June 2, 2016 following the U.S. Food and Drug Administration advisory on Opioid pain medicines.

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